K121620

DEC 11 2012

510(k) Summary

Owner Information

1) Name: DMETEC CO., LTD.

2) Address: 402-603 Techno-Park, 193 Yakdae-Dong, Wonmi-Ku, Bucheon City, KOREA

3) Phone Number: 82-32-234-0011

4) FAX Number: 82-32-234-1444

5) Name of Contact Person: Hong-Geun, Lee

6) Date the Summary was Prepared: 05/11/2012

Device Information

1) Common Name: Bone cutting instrument and accessories

2) Trade Name: Ultrasonic Surgery

3) Model Number(s): SmarThor

4) Classification Name: Drill, Bone, Powered

5) Regulation Number: 872.4120

Predicate Device Information

1) 510(k) Number: K072146

2) Trade Name: EMS Piezon Master Surgery

3) Product Code: DZI

Description of the Device

This product is a device using by purpose of bone cutting, polishing when operate implant for dentist's office using ultrasonic vibration because it is supplied electric and water in outside

Specifications of unit:

Model:	SmarThor
Supply voltage:	DC 24V
Supply frequency:	50 / 60 Hz
Power input:	24 VA
Device life	5years
Output characteristics(Ultrasonic output):	Maximum output power with load:50W Frequency range available: 24-32kHz.
Type of protection against electric shock:	Class 1, with transformer
Degree of protection against electric shock:	Applied part type BF
Specification of transformer	AC100-250V, 50-60Hz
Output characteristics of transformer:	DC 24V

Intended Use

The device is intended for use in surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.

1) Product Name: Ultrasonic Surgery
2) Model: SmarThor

Summary of Technical Characteristics Compared to the Predicate Device

	DMETEC (SmarThor)	**EMS** (Piezon Master Surgery)
510(k) reference	-	K072146
Indication for use	The device is intended for use in surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.	The EMS Piezon Master Surgery is an ultrasonic bone-cutting instrument for use in surgical dentistry
UNIT		
Supply voltage	24V DC	100-240 V AC
Power consumption(max)	50W max	105VA
OUTPUT CHARACTERISTICS		
Maximum output power with load	50W	25W
Frequency range available	24-32 kHz	24-32 kHz
TRANSFORMER		
Input	100-240 VAC, 50-60Hz	100/220 VAC/50-60Hz
Output	24V DC/ 2.7A	24V AC/ 1.25A
MAIN COMPONENT		
	1 Unit Body 1 Hand-piece 1 Tip	1 Unit Body 1 Hand-piece 5 Tips
MATERIAL		
Tip(contact with patient)	Stainless steel	Stainless steel

Brief Discussion of Nonclinical Tests (if applicable)

For biocompatibility, in vitro cytotoxicity test, skin sensitization test and oral mucosa irritation test were conducted. During the in vitro cytotoxicity test, no evidence of causing cell lysis or toxicity was found and it was evaluated as Grade 0 on the criteria of ISO 10993-5:2009. As for skin sensitization, sensitization scores were zero and the sensitization rates were observed 0% at 24 hours. As for oral mucosa irritation test, no mortality was observed, no changes in body weight were observed, and there were no differences in saline and test group.

For electric safety and electromagnetic compatibility, the device was tested according to IEC 60601-1:1988 + A1:1991 + A2:1995 and IEC 60601-1-2: 2007 and the device was found to meet the requirements of the standards.

Software validation report shows that the device is substantially equivalent and performs as it should.

Brief Discussion of Clinical Tests (if applicable)

Comparison with the predicate indicates they are similar in functions and efficiency, and the post market experience proves that it is substantially equivalent.

Conclusion from Nonclinical and Clinical Tests (if applicable)

Biocompatibility tests, electric safety test and electromagnetic compatibility test show that the device meets the requirements of those standards.

Literatures and post market experience show that the device is substantially equivalent.

Comparison with the predicate device shows that the device has similar specification and performance.

Thus, we conclude that SmarThor are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

DMETEC Company, Limited
C/O Mr. Daniel Nam
General Manager
PATS Corporation
4568 West 1ST Street, Suite 104
Los Angeles, California 90004

Re: K121620
Trade/Device Name: Ultrasonic Surgery (SmarThor)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: November 14, 2012
Received: November 23, 2012

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121620

Device Name: Ultrasonic Surgery (SmarThor)

Indications For Use: The device is intended for use in surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.11 13:22:33 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____